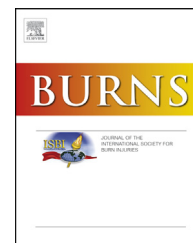


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A bio-degradable synthetic membrane to treat superficial and deep second degree burn wounds in adults and children – 4 year experience

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ABSTRACT

Introduction: A new bio-degradable synthetic membrane was recently introduced to treat second degree burns in adults and pediatric patients.

Objective: To assess complications and outcomes using this absorbable synthetic membrane to treat second degree burns.

Methods: 229 burn patients, 138 pediatric, with superficial and deep second -degree wounds, treated with the absorbable synthetic membrane (Suprathel[®], Polymedics, Denkendorf, Germany) were included in this study. Patients were treated under anesthesia or moderate sedation. The wound bed was prepared by using either rough debridement or dermabrasion excision. After hemostasis, the membrane was applied to the wound with an outer layer dressing of fatty gauze, bridal veil, absorptive gauze and an ACE[®] wrap. The outer dressing was removed every one to four days, depending on exudate, in order to closely follow the wound through the translucent membrane and fatty gauze layers. After complete epithelialization, the dressing separated and could be removed. The study focused on the need for subsequent grafting, healing time, patient pain level, hypertrophic scarring and rate of infection.

Results: All wounds in this study that were treated with Suprathel[®] healed without grafting. The average TBSA (Total Body Surface Area) was 8.9% (1%-60%). Average time to healing was 13.7 days for $\geq 90\%$ epithelialization with 11.9 days for pediatric patients versus 14.7 days for adults. Throughout the treatment period, the average pain level was 1.9 on a 10-point scale. 27 patients developed hypertrophic scarring in some areas (11.7%). Average Length of stay (LOS) was 6.9 days. The rate of infection was 3.8% (8/229). Failure or progression to full thickness in part of the wounds was 5.2% (12/229).

Conclusion: In treating second degree burn wounds, this membrane provides a simple, effective solution alternative with good outcomes and less pain than conventional and previously studied treatment options in the same institution. Fewer dressing changes and easier overall management of the wounds contribute to its favorable profile.

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1. Introduction

Second degree burns are the most common burn injuries world-wide, especially in children. Most second degree burns heal without surgical intervention, but the prevention of desiccation, wound conversion and infection are pivotal for the long-term outcome. While daily dressing changes with a variety of antimicrobial ointments are the standard treatment for these types of burns, these dressing changes are painful and may require opioid pain medication and large quantities of dressing materials until the wounds are healed. The ointment carrying gauzes do not stay in place well around major joints and the abdomen and frequently lead to burn wound exposure in these areas. In larger body surface area second degree burns, the fluid management and systemic inflammatory response require close monitoring and prolonged hospital stay. Temporary skin coverage solutions (xenograft, allograft, amniotic membrane, Biobrane[®], Transcyte[®], Mepitel[®], etc.) have been studied in the past [1,2,9–14], attempting to limit the number of painful dressing changes, decrease the systemic response and accelerate the rate of healing. The major drawbacks have been the rate of infection and integration of the temporary coverage material into the wound bed. Depending on the depth of the injury (superficial or deep second degree), allodermis and xenodermis may vascularize and integrate permanently, leaving an ugly scar, or cause a delayed rejection reaction, opening previously epithelialized areas once again and also cause systemic rejection symptoms. All biologic membranes carry the risk of slow virus or other infections, even when properly processed. The availability is limited by appropriate donors. In some cultural and religious contexts organ donation or xenograft use is not permitted. Some of the previously extensively used and studied skin substitutes are no longer available or only available off and on. Most other advanced dressings are not translucent and need to be changed several times during the wound healing process, causing pain and anxiety. Furthermore, final outcome reports of these temporary skin substitutes and membranes beyond wound healing and epithelialization are scarce [13,14].

When treating second degree burns, the ideal treatment would decrease pain, limit dressing changes, allow assessment of the healing progress, prevent infection, accelerate healing, improve long-term outcomes, and save on treatment costs. Suprathel[®] seems to fulfill most out of these mentioned requirements [2–7]. Cost assessment depends on the size and location of the burn wound and the treatment setting.

Suprathel[®] is a porous, fully synthetic biodegradable copolymer membrane made of DL-lactide, which is FDA registered. It conforms to the surface it is applied to as soon as it absorbs moisture [2,6]. It degrades into lactic acid, which is instantly buffered by wound exudate, creating a physiologic cell growth environment. After application of this membrane, dressing changes are limited to outer dressings. The wound is no longer exposed during dressing changes, which keeps the related pain experience for the patient low [6]. If the wound epithelializes before it is fully degraded, it separates from the healed skin without ingrowth. Suprathel[®] has been studied and used in Europe extensively over the past 16 years (it was approved in 2004) [18–21]. This membrane was used at Lehigh

Valley Health Network (LVHN) Regional Burn Center shortly after it was available in the United States.

When compared to other skin substitutes and advanced dressings for partial thickness burns, Suprathel[®] had favorable outcomes in previous studies [2,4]. The goal of this retrospective chart review was to summarize the experiences at LVHN Regional Burn Center with this DL-lactide membrane and quantify possible complications in this institution.

2. Materials and methods

The retrospective chart review encompassed a 4-year study period from September 1st, 2013 to May 31st, 2017 with patients treated for acute burns at the Regional Burn Center at LVHN between September 1st, 2013 and December 31st, 2016. IRB approval was obtained. Patient data was compiled from in- and outpatient medical records (CPO & CE & EPIC). Included were those who had received Suprathel[®] temporary skin substitute.

2.1. Skin substitute

Suprathel[®] is an absorbable synthetic membrane produced from a copolymer mainly consisting of DL-lactide (>70%), trimethylenecarbonate, and ϵ -caprolactone. It represents a synthetic dressing that imitates the properties of a natural epithelium. The membrane and the manufacturing process have been patented (US 6 706 058). The final product consists of a membrane with 80% porosity resulting in symmetrical pore cross-sections. Pore sizes vary between 2 and 50 μ m. The membrane has an elongation capacity of up to 250% with a modulus of less than 800 N-mm². This offers a large amount of plasticity with instant adaptation to wound bed and contour at body temperature. Its moisture permeability prevents accumulation of wound fluid supporting wound healing and re-epithelialization. In the wound healing process, the molecular weight decreases, and the dressing detaches from the wound surface. During re-epithelialization, the membrane becomes translucent which allows the evaluation of the wound bed without manipulation of the wound dressing itself. When applied on burns, it is recommended to cover Suprathel[®] with one layer of paraffin gauze (or similar), a non-adherence layer like Dermanet[®] and an additional layer of absorbent gauze. This will protect the dressing and prevent material dislocation.

2.2. Inclusion criteria

All charts from patients that suffered a burn injury and were admitted to the Lehigh Valley Health Network Regional Burn Center between September 1st 2013 and December 31st 2016 were included in this study. Only charts from patients who received the synthetic membrane to some, or all of their burn wounds were reviewed. Data collection continued to June 2017 for outcome parameters.

2.3. Treatment protocol

After wound evaluation by the burn surgeons, proper consent and under moderate sedation or anesthesia, either in the

operating room or the treatment room, dermabrasion or rough debridement was performed under sterile conditions. Wounds were rinsed with a sterile saline solution and dabbed dry. The Suprathel[®] membrane was applied and covered with fatty gauze (Xeroform[®], Vaseline[®] gauze or Curity[®] or Rylon[®]), a non-adherent veil (Dermanet[®], N-terface[®]), an absorbent gauze, and an Ace[®] bandage, Coban[®], or surgical netting. The outer dressings, down to the veil, were changed every 1–4 days. (Fig. 1 a-1e). After discharge from the inpatient setting, patients were routinely followed weekly until wound healing. Once the wound was completely healed and epithelialization was achieved, the dressing began to separate and was removed. Routine follow up appointments thereafter were monthly and 3-monthly to assess scarring, if necessary, as is standard in our institution.

2.4. Data collection

Data from in- and outpatient patient records were retrospectively collected: depth of injury, age and gender, length of stay

in hospital, pain scores (Visual Analog Scale), incidence of infection, healing time, incidence of failure or wound conversion and long term hypertrophic scarring (as determined by the PI or the two Nurse Practitioners evaluating all outpatients at LVHN) were collected and entered into Microsoft Excel. Specifically, failure was determined by need for further dressing of wound areas as documented in the record, wound conversion was determined by need for skin grafting and the photographic documentation in the patient record, as was hypertrophic scarring. All evaluations were performed by either the PI or one of the two outpatient providers with photograph confirmation by the PI.

2.5. Statistical analysis

Descriptive statistics according to the outcome parameters taken from the in- and outpatient records were analyzed using Microsoft Excel[®]. A Spearman's rank order (ρ) correlation was performed on the data. This nonparametric test was chosen because of small sample sizes (e.g. only 12 patients

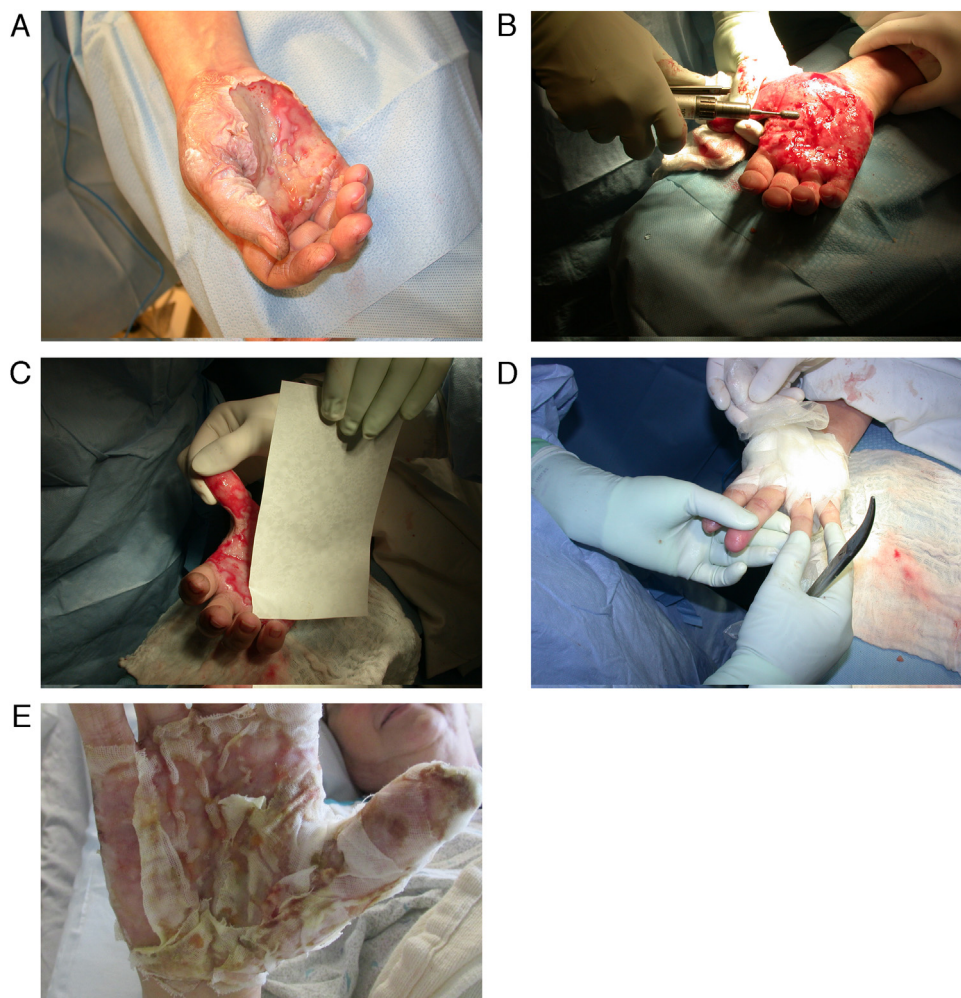


Fig. 1 – a -eTechnique of Suprathel application and dressing.

1a – Palm of hand burn deep 2nd degree before debridement.

1b – Palm of hand burn dermabrasion.

1c – Palm of hand burn application of Suprathel[®] bio-degradable membrane.

1d – Palm of hand burn fatty gauze and veil application over membrane.

1e – Palm of hand burn outer dressing removed day 2 post application of Suprathel[®].

Table 1 – Detailed results patients treated with Suprathel®.

| Parameter | Total N = 229 | Pediatric N = 138 | Adult N = 91 | OR applied N = 158 | Burn Center Treatment Room applied N = 71 |
|---|------------------|----------------------|-----------------|-----------------------|--|
| Male/Female | 141/88 | 79/59 | 62/29 | 99/59 | 42/29 |
| Age (years) | 18 | 4.4 | 37.6 | 21.8 | 8.5 |
| TBSA (%) | 8.9 | 7.06 | 11.5 | 10.45 | 5.3 |
| Time to Heal (days) | 13.7 | 12.3 | 16.4 | 15.2 | 11 |
| Pain (x/10 VAS) | 1.9 | 0.6 | 2.7 | 1.8 | 0.5 |
| LOS (days) | 6.9 | 4.8 | 10.2 | 8.9 | 2.5 |
| Infection (%) | 3.8 | 0 | 8.79 | 4.43 | 1.4 |
| Failure/Progression to full thickness (%) | 5.2 | 2.9 | 8.79 | 7.59 | 0 |
| Hypertrophic scar (%) | 11.7 | 10.1 | 14.3 | 15.2 | 4.2 |

were reported with Suprathel failures) and because the requirements for normality are more relaxed. An alpha level of $\alpha = .05$ was chosen.

Data were stored de-identified and in a secure research drive.

3. Results

3.1. Demographics

A total of 229 patients (141 male, 88 females, (138 pediatric)) with a mean age of 18 years (9 weeks to 73 years) were included in the study. 474 sheets of the synthetic membrane were applied to second degree burns (superficial and deep). The average burn size was 8.9% (range 1 to 60% TBSA).

3.2. Measured parameters

All wounds that received Suprathel® healed without the need for grafting (in a large number of patients treated in the operating room, excision and split thickness skin grafting was performed to the deeper burn wounds at the same time as dermabrasion and Suprathel® application to the more superficial wounds). The average time to healing was 13.7 days to achieve at least a rate of 90% re-epithelialization. Pediatric patients healed faster (12.3 days). Throughout the study, the reported average pain score was 1.9 on a 10-point Visual Analog Scale (VAS). Hypertrophic scarring occurred in some areas of the burn in 27 patients of 229. However, only 158 patients required follow up past the healing phase. It was assumed that 71 patients who did not follow up were discharged because they had no scarring in need for treatment (hypertrophic scarring or contracture scarring) or any other concerns. This assumption was made because it is standard of care at LVHN Burn Center to follow all patients throughout their recovery and re-integration process. Because of the integrated scar treatment program, which includes capabilities for all reconstructive procedures in the outpatient burn center, most patients are followed for several years, if scars result. Infection occurred in 8 patients (3.8%). The rate of failure or progression to full-thickness wounds in any area of the burn was 5.2% (12 patients). See [Table 1](#) for more detailed results.

Failure of Suprathel® or progression of wounds was statistically significantly correlated with increased level of depth of burn ($r = -0.231, p < .01$, one tailed), increased likelihood of wound infection ($r = .273, p < .001$, one-tailed), increased likelihood of hypertrophic scarring ($r = .141, p < .05$, one tailed), gender (males are more likely to have a failure, $r = -0.139, p < .05$, one tailed), higher number of consumed units (= more severe burn) ($r = .141, p < .05$, one tailed), where applied (higher rate of failure when done in the OR, $r = .159, p < .01$, one tailed), and increased pain level ($r = -0.113, p < .05$, one tailed). ([Table 5](#))

Table 2 – Transcyte®: Summary Statistics by Burn site.

| N (%) | Topical n (%) | Operative n (%) | Overall n (%) |
|----------------------|------------------|--------------------|------------------|
| Age | | | |
| < = 5 years | 1 (4.0) | 19 (14.2) | 20 (12.6) |
| 6–12 years | 2 (8.0) | 18 (13.4) | 20 (12.6) |
| 13–25 years | 0 (0.0) | 21 (16.4) | 22 (13.8) |
| 26–45 years | 7 (28.0) | 31(23.1) | 28 (23.9) |
| 46–60 years | 12 (48.0) | 37 (27.6) | 49 (30.8) |
| >60 years | 3 (12.0) | 7 (5.2) | 10 (6.3) |
| Total | 25 | 134 | 159 |
| Sex | | | |
| Male | 22 (88.0) | 86 (64.2) | 108 (67.9) |
| Female | 3 (12.0) | 48 (35.8) | 51 (32.1) |
| Total | 25 | 134 | 159 |
| Race | | | |
| White | 21 (84.0) | 125 (93.3) | 146 (91.8) |
| Non-white | 4 (16.0) | 9 (6.7) | 13 (8.2) |
| Total | 25 | 134 | 159 |
| Burn Depth | | | |
| 2nd Degree | 17 (68.0) | 88 (65.7) | 105 (66.0) |
| Deep 2nd Degree | 8 (32.0) | 46 (34.3) | 54 (34.0) |
| Total | 25 | 134 | 159 |
| Visible Scars | | | |
| None | 8 (32.0) | 51 (38.1) | 59 (37.1) |
| Any | 17 (68.0) | 83 (61.9) | 100 (62.9) |
| Total | 25 | 134 | 159 |

Table 3 – Transcyte[®]: Type of Scar, by Treatment Group.

| | Topical | Operative | Overall | Risk Ratios ^a | |
|-----------------------------|-----------|-----------|-----------|--------------------------|---------------|
| | n(%) | n(%) | n(%) | RR | 95% CI |
| No visible scar | 8 (32.0) | 51 (38.1) | 59 (37.1) | 1.0 | – |
| Atrophic scar | 10 (40.0) | 48 (25.8) | 58 (36.5) | 1.12 | (0.66, 1.90) |
| Hypertrophic or keloid scar | 6 (24.0) | 31 (23.1) | 37 (23.3) | 1.04 | (0.48, 2.22) |
| Visible scar NOS | 1 (4.0) | 4 (3.0) | 5 (3.1) | 1.34 | (0.16, 11.50) |
| Total | 25 | 134 | 159 | | |

^a Risk ratios (RR) were calculated using the topical group with no visible scarring as the baseline for comparison.

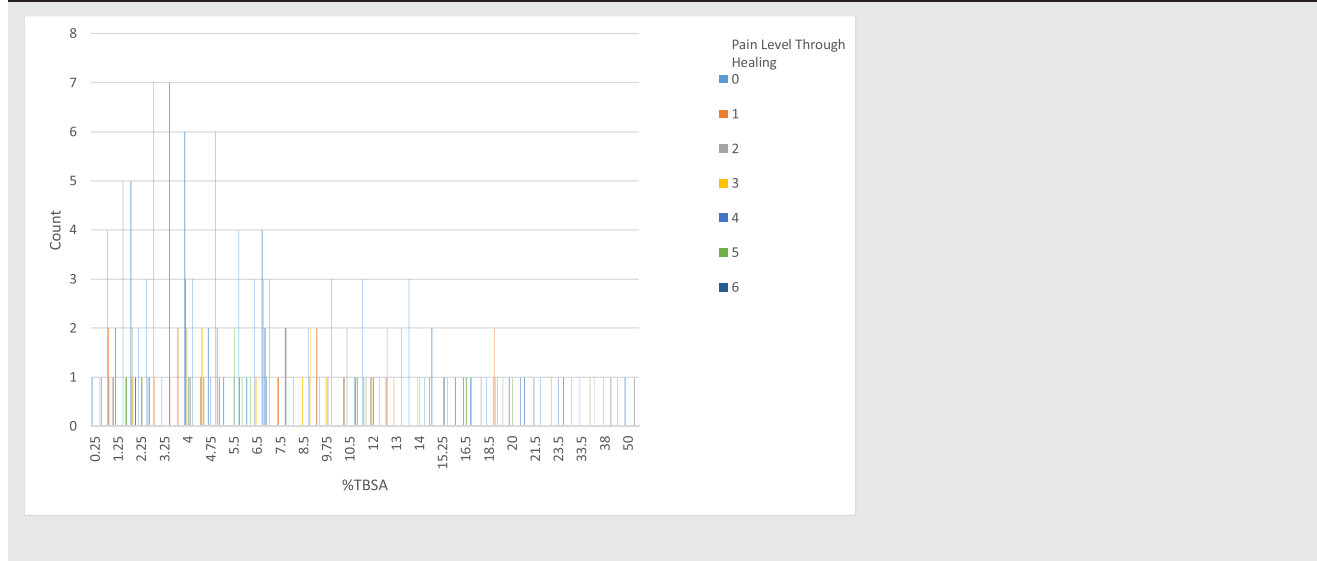
Table 4 – Transcyte[®]: Number of Days to 90% Closure, by Treatment Type and Age.

| Age Category | Topical | | Operative | | Overall | |
|--------------|---------|-------------|-----------|------------|---------|-------------|
| | n | Mean (+SD) | n | Mean (+SD) | n | Mean (+SD) |
| <= 5 | 1 | 10 (0) | 19 | 14.2 (3.7) | 20 | 14 (3.7) |
| 6–12 | 2 | 10 (0) | 18 | 13.9 (4.6) | 18 | 13.9 (4.6) |
| 13–25 | 0 | 0 (0) | 22 | 17.4 (9.9) | 22 | 17.4 (9.9) |
| 26–45 | 5 | 17.6 (7.7) | 31 | 19.7 (6.3) | 36 | 19.4 (6.4) |
| 46–60 | 12 | 27.9 (48) | 36 | 17.8 (6.7) | 48 | 20.3 (24.3) |
| >60 | 3 | 14.3 (4.6) | 7 | 18.3 (6.8) | 10 | 17.1 (6.3) |
| Total | 23 | 21.6 (34.9) | 133 | 17.2 (6.9) | 156 | 17.8 (14.7) |

Table 5 – Correlation analysis.

| | | Correlations | | | | | | | | | | | | |
|----------------------------------|-------------------------|-------------------------|----------------------------------|-----------------------------|-------------------------------|---------|------------------------|--------|-----------------|-----------------------|---------------------|---------------------------------|----------------------------|---------|
| | | Depth of Burn (1, 2, 3) | Failure of Suprathel? 1=Yes 2=No | Wound Infection? 1=Yes 2=No | Hypertrophic scars 1=Yes 2=No | Age | Gender =Male; 2=Female | %TBSA | Date of Surgery | Length of Stay (Days) | # of Consumed Units | Where Applied (OR/BC) 1=OR 2=BC | Pain Level Through Healing | |
| Spearman's rho | Depth of Burn (1, 2, 3) | Correlation Coefficient | 1.000 | -.231** | -.296** | .084 | .120* | -.005 | -.078 | .141* | .061 | -.079 | -.037 | .044 |
| | | Sig. (1-tailed) | | .000 | .000 | .213 | .036 | .470 | .122 | .017 | .183 | .161 | .288 | .281 |
| | | N | 225 | 214 | 215 | 156 | 225 | 224 | 224 | 224 | 157 | 225 | 217 | 217 |
| Failure of Suprathel? 1=Yes 2=No | | Correlation Coefficient | -.231** | 1.000 | .273** | .141* | -.084 | -.139* | .030 | .137* | -.073 | .141* | .158** | -.113* |
| | | Sig. (1-tailed) | .000 | | .000 | .039 | .110 | .020 | .329 | .022 | .142 | .040 | .010 | .049 |
| | | N | 214 | 217 | 216 | 158 | 217 | 217 | 216 | 216 | 156 | 217 | 216 | |
| Wound Infection? 1=Yes 2=No | | Correlation Coefficient | -.296** | .273** | 1.000 | .060 | -.184** | -.093 | .005 | -.033 | -.086 | -.016 | .073 | -.244** |
| | | Sig. (1-tailed) | .000 | .000 | | .229 | .003 | .086 | .469 | .312 | .102 | .421 | .140 | .000 |
| | | N | 215 | 216 | 219 | 157 | 219 | 219 | 218 | 218 | 157 | 219 | 217 | |
| Hypertrophic scars 1=Yes 2=No | | Correlation Coefficient | .064 | .141* | .060 | 1.000 | -.199** | .089 | -.096 | .186** | -.272** | .002 | .236** | -.035 |
| | | Sig. (1-tailed) | .213 | .039 | .229 | | .006 | .132 | .116 | .010 | .000 | .492 | .001 | .332 |
| | | N | 156 | 158 | 157 | 158 | 158 | 158 | 157 | 157 | 158 | 103 | 158 | 157 |
| Age | | Correlation Coefficient | .120* | -.084 | -.184** | -.199** | 1.000 | -.106 | .276** | -.155** | .399** | .285** | -.362** | .497** |
| | | Sig. (1-tailed) | .036 | .110 | .003 | .006 | | .054 | .000 | .010 | .000 | .000 | .000 | .000 |
| | | N | 225 | 217 | 219 | 158 | 230 | 229 | 228 | 228 | 161 | 229 | 221 | |
| Gender =Male; 2=Female | | Correlation Coefficient | .005 | -.139* | -.093 | .089 | -.106 | 1.000 | -.027 | .002 | -.032 | -.100 | .025 | -.005 |
| | | Sig. (1-tailed) | .470 | .020 | .086 | .132 | .054 | | .345 | .488 | .318 | .104 | .352 | .470 |
| | | N | 224 | 217 | 219 | 158 | 229 | 229 | 227 | 227 | 161 | 228 | 221 | |
| %TBSA | | Correlation Coefficient | -.078 | .030 | .005 | -.096 | .276** | -.027 | 1.000 | -.196** | .498** | .597** | -.285** | .151* |
| | | Sig. (1-tailed) | .122 | .329 | .469 | .116 | .000 | .345 | | .001 | .000 | .000 | .000 | .013 |
| | | N | 225 | 216 | 218 | 157 | 228 | 227 | 228 | 227 | 160 | 228 | 220 | |
| Date of Surgery | | Correlation Coefficient | .141* | .137* | -.033 | .186** | -.155** | .002 | -.196** | 1.000 | -.303** | -.088 | .578** | -.275** |
| | | Sig. (1-tailed) | .017 | .022 | .312 | .010 | .010 | .488 | .001 | | .000 | .134 | .000 | .000 |
| | | N | 224 | 216 | 218 | 157 | 228 | 227 | 227 | 228 | 161 | 228 | 220 | |
| Length of Stay (Days) | | Correlation Coefficient | .061 | -.073 | -.086 | -.272** | .399** | -.032 | .498** | -.303** | 1.000 | .120 | -.632** | .272** |
| | | Sig. (1-tailed) | .183 | .142 | .102 | .000 | .000 | .318 | .000 | .000 | | .065 | .000 | .000 |
| | | N | 224 | 216 | 218 | 158 | 228 | 227 | 227 | 227 | 160 | 228 | 220 | |
| # of Consumed Units | | Correlation Coefficient | -.079 | .141* | -.016 | .002 | .285** | -.100 | .597** | -.088 | 1.000 | -.088 | .127 | |
| | | Sig. (1-tailed) | .161 | .040 | .421 | .492 | .000 | .104 | .000 | .134 | .065 | | .197 | .055 |
| | | N | 157 | 156 | 157 | 103 | 161 | 161 | 160 | 161 | 160 | 161 | 160 | |
| Where Applied (OR/BC) 1=OR 2=BC | | Correlation Coefficient | -.037 | .158** | .073 | .236** | -.362** | .025 | -.285** | .578** | -.632** | 1.000 | -.341** | |
| | | Sig. (1-tailed) | .288 | .010 | .140 | .001 | .000 | .352 | .000 | .000 | .000 | .197 | | .000 |
| | | N | 225 | 217 | 219 | 158 | 229 | 228 | 228 | 228 | 161 | 229 | 221 | |
| Pain Level Through Healing | | Correlation Coefficient | .044 | -.113* | -.244** | -.035 | .497** | -.005 | .151* | -.275** | .272** | .127 | 1.000 | |
| | | Sig. (1-tailed) | .261 | .049 | .000 | .332 | .000 | .470 | .013 | .000 | .000 | .055 | .000 | |
| | | N | 217 | 216 | 217 | 157 | 221 | 221 | 220 | 220 | 160 | 221 | 221 | |

** Correlation is significant at the 0.01 level (1-tailed).
* Correlation is significant at the 0.05 level (1-tailed).

Table 6 – Pain throughout healing by %TBSA.

4. Discussion

The challenges in treating partial thickness burn wounds remain to be high pain levels resulting from daily dressing changes and unpredictable scarring and healing times. As observed by Hildebrandt et al., the adherence of Suprathel[®] to the wound bed as well as its permeability helps to prevent infection and increases healing which allows for a quick re-epithelialization time [8].

When comparing Biobrane[®] and Suprathel[®] in treating second degree burns, equivalent outcomes were found by Rahmanian-Schwarz et al. [2]. Their outcome measurements were healing time and an eight-month follow-up scar evaluation using the Vancouver Scar Scale and Cutometer measurements [2]. Keck et al. found a better scar outcome in their early results in a prospective study comparing Suprathel[®] to Split Thickness Skin Graft (STSG) for deep dermal hand burns in adults [3]. In 2011, a side by side prospective study found that there was significantly less bleeding, pain, and equal epithelialization time in Suprathel[®] treated STSG donor sites when compared to Mepilex[®] Transfer treated donor sites [4]. When comparing conventional cream dressings with Mepitel AG[®] however, Moulton et al. found significant delay in healing in the Mepitel AG[®] treated group of pediatric burns, probably due to desiccation [14]. This raises an aspect in the evaluation of temporary skin substitutes and advanced dressings only recently discussed: the ambient humidity, which may lead to significantly different results in different geographical regions. Another study applied Suprathel[®] to second degree burn wounds, frostbite wounds and Lyell disease skin slough and reported good success with an approximate 75% healing rate within 21 days [5]. A series of 33 pediatric burn treatments used Suprathel[®] as the temporary skin substitute and found good results in dermal and deep dermal burns with only four cases of hypertrophic scarring, all of which the authors attributed to secondary wound infection [6]. Lastly, in 2014, the use of a hand-shaped Suprathel[®]

application (as opposed to rectangular shaped sheets) for hand burn applications reported significant time savings during the procedure [7].

The higher conversion/failure rate if Suprathel[®] was applied in the operating room can probably be explained by the fact that more severe burns overall were taken to the operating room and a decision between split thickness skin grafting and membrane coverage was anticipated. At the same time, the pain level increased because some areas in that patient group were skin grafted and donor site pain skewed the pain assessment in the chart. Because of the retrospective nature of this study, no area specific pain assessment was available, making it impossible to distinguish between Suprathel[®] covered burn area versus donor site versus grafted burn area (Table 6).



Fig. 2 – First dressing change after combination split thickness skin graft and Suprathel[®] for combination 3rd degree and 2nd degree burn treatment in one operative procedure 5 days prior.

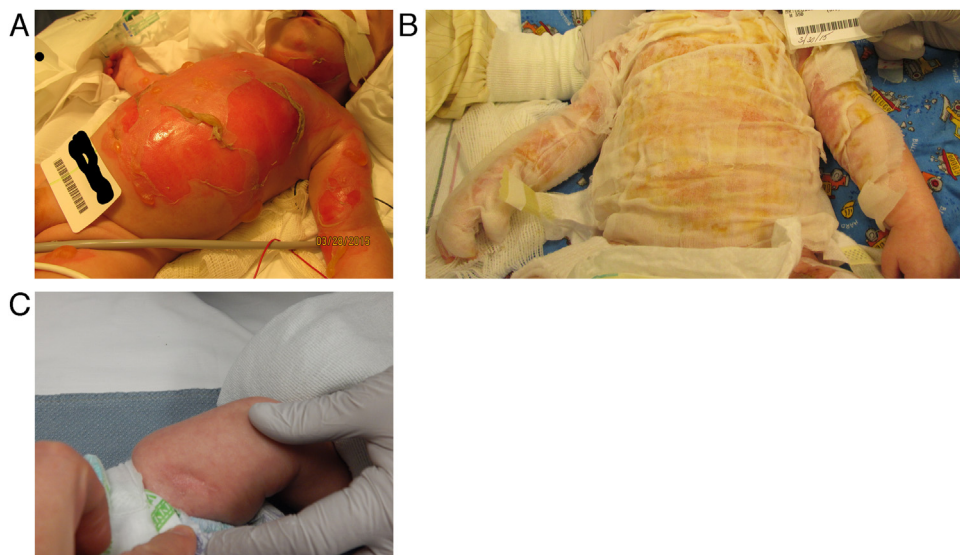


Fig. 3 – a -c 9- week old infant with 26% TBSA.

3a - on admission, note left upper thigh burn.

3b – outer dressing change 2 days after application of Suprathel[®] to all burns, note left upper thigh burn exposed from diaper movement and desiccated.

3c – left upper thigh scarring (25.5% TBSA healed without scarring).

The positive correlation of male gender and failure in this group was due to the more severe burn in the patients who had failure, which were mostly male (only 12 patients total).

Taking all this into consideration, the synthetic copolymer dressing, Suprathel[®] was evaluated in this patient population retrospectively over 4 years, after the previously used temporary skin substitute was no longer available (Transcyte[®]), which was, equivalent to Dermagraft[®] in larger sheets, cryopreserved human fibroblast derived dermal substitute; it was composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold (Biobrane[®]).

This study assessed a variety of outcome parameters (pain scores (according to a VAS), incidence of infection, healing time, and hypertrophic scarring) and found favorable results. Although some small areas of wound conversion were observed, no grafting was required in the current study group. The healing rate with > 90% rate of epithelialization was achieved within 13.7 days. The healing time was skewed unfavorably due to the fact that outer dressings were only changed every 2–4 days. The rate of infection was minimal at 3.8%. and a low VAS pain score was reported by all treated patients. This could be attributed to a reduction in dressing changes as well as the flexibility of the skin substitute and its favorable wound milieu (near physiologic skin pH). Hypertrophic scarring was noted in only 27 patients and most of these scars represented only a small area of the initial burn (Fig. 4). Hypertrophic scarring occurs based on the initial depth of injury, as extensively studied by Tredget et al. [15], but also based on genetic predisposition, hormonal constitution and in areas of the burn wound that become exposed to desiccation or other irritation. Most of the hypertrophic scarring observed in this patient population occurred in such areas as body creases

and perineum, which are notorious for dressing difficulty, especially in children (Fig. 3a-3c) In Keck's study on deep dermal burns patients also reported that their Suprathel[®]-treated areas had a more natural appearance in terms of scarring [3]. A large follow-up study (IRB approved, retrospective review and prospective scar measurements), looking at outcomes after treatment of second degree burns in adults and children in 2007 was performed at the same institution. Assessed were 159 patients 1 year post treatment of second degree burns in the LVHN burn center, comparing topical cream dressings (double antibiotic ointment and fatty gauze



Fig. 4 – Left wrist and left upper outer thigh hypertrophic scarring where Suprathel[®] was dislodged during healing process.

every 24 h) to Transcyte[®], using the exact same procedure as in this study of sterile wound preparation by rough debridement or dermabrasion excision, followed by undisturbed wound healing under the skin substitute (the same surgeons were performing the procedures). Although the topical treatment group was small, the data clearly showed favorable results in the operative (Transcyte[®]) group over the topical cream dressing change group (Tables 2, 3, 4). This data was presented in 2008 at the American Burn Association meeting, but never published, because Transcyte[®] was taken off the market and there was no comparable skin substitute available in the United States, making these data seem irrelevant at the time. Looking at these data now, even less hypertrophic scarring and less scarring in general was seen in this Suprathel[®] group [16,17]. Obviously, a prospective comparative study between Transcyte[®] and Suprathel[®] should be initiated if and when Transcyte[®] becomes available again. One main result of both studies was however, that most second degree burns will leave some scarring, in opposition to prevailing opinions, if only pigment changes or microscopic structural changes.

Limitations of this study include the common limitations of any retrospective data analysis as well as the lack of a control group. The relatively long hospital stay in this group is due to the combination of split thickness skin grafting and Suprathel[®] application in one procedure in some patients (Fig. 2). Our future study groups will exclude those patients that need skin grafting for some or the majority of their wounds initially and include a topical cream treatment group.

5. Conclusion

The results of this retrospective review of using the polylactic acid membrane, Suprathel[®] over 4 years show that it is a good option when choosing a synthetic membrane to treat second degree burn wounds. This skin substitute offers a simplified treatment that provides a physiologic healing environment with good outcomes and less pain than previously used or studied options in the same institution by the same team of providers. It leads to a low incidence of infection, quick healing time, and a low pain level with no risk of ingrowth, disease transmission or cultural disagreement. A prospective long- term outcome study with control group is in preparation.

Conflict of interest/Disclosures

The authors have no financial disclosures or conflict of interest in relation to this manuscript.

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